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CHARACTERISTICS OF CHILDREN AND ADOLESCENTS USING PROTON PUMP INHIBITORS OR HISTAMINE-2-RECEPTOR ANTAGONISTS: ANALYSIS OF THIN AND PHARMO DATABASES

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OBJECTIVES: To describe demographics and co-morbidities of children starting PPI or H2RA use. **METHODS:** Data were obtained from The Health Improvement Network (THIN, a UK primary care database) and the Dutch PHARMO Database Network (including outpatient pharmacy and hospital databases). Children (<19 years) starting a PPI or H2RA between 2009–2012 (THIN) and 2008–2010 (PHARMO) were selected. Demographics, medical history, co-morbidities and co-medication were assessed. **RESULTS:** The study included 15782 PPI starters (THIN, n=5957; PHARMO, n=9825) and 8980 H2RA starters (THIN, n=5696; PHARMO, n=3284). The proportion of males was similar between PPI and H2RA starters in each database (THIN, 41% vs 48%; PHARMO, 44% vs 48%). H2RA starters more often were <12 years of age (THIN, 73% vs 26%; PHARMO, 58% vs 36%) and PPI starters more often had received other prior acid-suppressing treatment (THIN, 9% vs 2%; PHARMO, 10% vs 7%). In THIN, a history of infectious or respiratory disease was more common in PPI starters: infectious disease, 89% vs 65% (odds ratio (OR) 1.20; 95% confidence interval (CI) 1.05–1.37); respiratory disease, 77% vs 49% (OR 1.20; 95%CI 1.08–1.34). In PHARMO, PPI starters were also more likely to suffer from asthma/chronic obstructive pulmonary disease (8% vs 6% (OR 1.35; 95%CI 1.14–1.60)) and more often used antibiotics (20% vs 13% (OR 1.53; 95%CI 1.37–1.72)) and non-steroidal anti-inflammatory drugs (25% vs 5% (OR 4.48; 95%CI 3.80–5.29)). PPI starters in PHARMO were also more likely to have a history of diabetes or epilepsy (diabetes, 1% vs <0.5% (OR 5.00; 95%CI 2.33–10.73); epilepsy, 2% vs 1% (OR 1.69; 95%CI 1.16–2.45)). **CONCLUSIONS:** Results from both databases indicated that H2RA starters were younger than PPI starters. PPI starters were more likely to have received other prior acid-suppressing treatment and had more co-morbidities than H2RA starters.

PGI8

HEPATOCELLULAR CARCINOMA: AN EPIDEMIOLOGICAL AND MANAGEMENT SURVEY-BASED ANALYSIS IN ITALY

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OBJECTIVES: To verify how Hepatocellular Carcinoma (HCC) management is carried out in Italy and to point out the organizational key variables useful for an economic assessment, considering that Italy is among the European States with the highest incidence of HCC according to recent published data and that HCC is the final and highest cost health state along the natural history of liver diseases. **METHODS:** A questionnaire was set up jointly by clinicians (hepatologists and infectivologists), pharmacoeconomists and HTA experts, and submitted to 9 centers in order to collect epidemiology and management data. The survey consisted of a series of questions regarding HCC patients: gender and age, HCC etiology, BCLC (Barcelona Clinic Liver Cancer) staging at diagnosis, current treatments, hospitalization regimens, number and description of diagnostic/outpatient procedures, other relevant concurrent pathologies. The survey was administered to patients in four Italian centers of excellence for liver diseases with well-established experience in treating HCC patients. **RESULTS:** A total of 596 questionnaires were collected, the majority of which regarding male patients (79%), with a mean age of 67. Etiology proved to be mainly HCV-related (56%) and most patients underwent full hospitalization (81%) with a mean duration of 16.5 days, with a wide variability among centers, concerning both diagnostic procedures (CT, MRI, ecography...) and treatments (surgery, liver transplantation, drugs...). **CONCLUSIONS:** The collected data show a major heterogeneity, linked to the different etiology and epidemiology of the disease along the peninsula, well characterized by a number of published studies, but prove to be very helpful in describing the current situation regarding HCC in Italy. This descriptive analysis will be useful to set up a prospective study with the aim to implement an economic model able to compare different treatments and diagnostic procedures, and including organizational aspects in accordance to a cluster-randomized logic.

PGI9

INCIDENCE OF ANASTOMOTIC LEAKS AFTER COLORECTAL SURGERIES USING HOSPITAL EPISODE STATISTICS IN THE UNITED KINGDOM

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OBJECTIVES: Reported incidence of gastrointestinal anastomotic leaks after colorectal surgeries varies across regions, mainly due to different definitions of anastomotic leaks. A recent study using Premier Perspective administrative database reported 6.18% incidence of post-operative anastomotic leaks in US. The objective of this study is to apply a similar definition of anastomotic leaks from the US study and estimate incidence of anastomotic leaks after colorectal surgeries in UK. **METHODS:** Hospital Episode Statistics database was used to identify patients receiving colorectal surgeries from January 2007 to December 2011. The index colorectal surgeries included colectomy, hemicolectomy, sigmoid colectomy, and low anterior resection identified by OPCS-4 codes. The anastomotic leak event was defined by re-intervention (OPCS-4 codes) or diagnosis (ICD-10 codes) within 30-day window following index colorectal surgeries. The re-intervention included re-operation, re-anastomosis, stent, colostomy, image guided drainage, abscess, and washout. The diagnosis was generalized acute peritonitis. Chi-square and t tests were used to compare demographic characteristics between patients who had leaks and those who did not. **RESULTS:** A total of 132,045 patients (mean age: 65 years, 50% male) received colorectal surgeries during 2007–2011. Of these, 8,434 (6.38%) had anastomotic leaks within 30 days of the colorectal surgeries. 2.63% leak cases were defined by reoperation, 1.82% by diagnosis of generalized acute peritonitis, 1.24%

by colostomy, 0.9% by image guided drainage, 0.7% by washout, 0.62% by abscess, 0.42% by re-anastomosis, and 0.01% by stent. Patients with leaks tended to be slightly younger and male, had higher Charlson Co-morbidity Index, and more likely admitted through emergency vs. elective surgery (p<0.05). **CONCLUSIONS:** Our study indicated an incidence rate of 6.38% for post-operative anastomotic leaks among patients undergoing colorectal surgeries in UK, compared to 6.18% leak rate seen in the US study. The results highlight the importance of future study in evaluating the impact of anastomotic leaks on patient's clinical and economic outcomes in UK.

PGI10

RESOURCE USE AND DISEASE PROGRESSION AMONG HCV-POSITIVE PATIENTS

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OBJECTIVES: Hepatitis C is an infectious disease affecting the liver; chronic infection can lead to cirrhosis. The actual standard of care in Italy is Peginterferon+ribavirin. Our aim was to describe treatment patterns, disease progression and resource use in HCV. **METHODS:** An observational retrospective cohort analysis based on 4 Local Health Units administrative and laboratory databases was conducted. HCV-positive patients between January 1, 2009– December 31, 2010 were included and followed-up for one year. To explore which covariates were associated to disease progression (cirrhosis, hepatocellular carcinoma -HCC-, death for any cause), Cox proportional hazards models were performed. **RESULTS:** A total of 9514 patients were analyzed, 55.6% male, age 58.1±16.1; 5.8% had HIV, 3.0% HBV, 1.6% HCV+HBV+HIV, 26.1% cirrhosis, 4.3% HCC. Genotypes frequencies were 1a (17%), 1b (34%), 2 (24%), 3 (19%), 4 (5%). Antiviral treatment was not administered to the majority of patients (79%); the main factors affecting this decision were: age >65 years (44%), females (46% VS 40% of treated), cirrhosis (30%), normal liver enzymes (28%), ongoing substance/alcohol abuse (7%), HCC (5%). Disease progression in the observed timeframe was less frequent among treated patients (incidence rate per 100 patients/year: cirrhosis 2.1±0.7 VS 13.0±1.0, HCC 0.5±0.3 VS 3.6±0.5, death for any cause 0.5±0.3 VS 6.4±0.7); at multi-variable Cox regression models, hazard ratios were, respectively, 0.30 (0.21–0.43), 0.41 (0.19–0.92) and 0.24 (0.12–0.48) (all p<0.05). For genotype1 subgroup, results were not statistically different between Peginterferon+ribavirin treated and untreated (cirrhosis: HR=0.82 (0.32–2.11), p=0.682). The annual expenditure for HCV management (drugs, hospitalizations, outpatient services) was €4,700 per patient. **CONCLUSIONS:** Actual standard of care was not widely used, especially for sensitive subgroups such as women and the elderly; in this context, there is an urgent need for treatment, but current therapies do not appear to be adequate for all patients, especially those with genotype1, which represents 60% of the Italian HCV population.

GASTROINTESTINAL DISORDERS – Cost Studies

PGI11

PERITONITIS FLUID TREATMENT IN RUSSIAN FEDERATION: EVALUATION OF ECONOMICAL BURDEN IN REAL CLINICAL PRACTICE

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OBJECTIVES: Peritonitis is an inflammation of the parietal and visceral peritoneum which is accompanied by severe general condition of the body. Peritonitis as a complication of acute inflammatory diseases of the abdominal cavity is found in 15–20% of clinical observation and about 6% of all surgical procedures on the abdominal cavity. The research is conducted in regard to 4 technologies of fluid treatment, including: Reamberin, Ringer's solution, Plasma-Lyte and Sterofundin. **METHODS:** Retrospective researches analysis is considered as a source of data on real effectiveness. The decree of the RF Ministry of Health No 669 of October 15, 2007 is considered as a source of data on commonly used drugs and medical services. The price-list of the Clinical Center of the First MSU charges for medical services is incorporated as the source of data on the price of medical services. **RESULTS:** The calculation is made for the hypothetical group of 100 patients with the peritonitis disease. During the cost of illness analysis of peritonitis the direct costs are estimated. They include: medical services and pharmacotherapy in the period of the residence in the in-patient department(euro per patient: 9 241 for Reamberin, 10 554,8 for Ringer's solution, 9 755,7 for Plasma-Lyte and 9 756,4 for Sterofundin). The cost-effectiveness analysis(CEA) results are the following: 10 241 euro for Reamberin, 12 639 euro for Ringer's solution, 12 302 for Plasma-Lyte and 11 683 euro for Sterofundin. The budget impact analysis(BIA) show that the 100% switching patients from Ringer's solution, Plasma-Lyte and Sterofundin to Reamberin saves respectively: 131 377 euro, 51 465 euro and 51 538 euro. **CONCLUSIONS:** Cost of illness analysis, CEA and BIA of peritonitis indicate that the scheme of therapy including Reamberin is the dominant one. Total costs are 9 241 euro per patient, CER is 10 241 euro per saved live.

PGI12

ORGANIZATIONAL AND ECONOMIC ISSUES RELATED TO THE INTRODUCTION OF BOCEPREVIR IN THE TREATMENT OF PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS C IN ITALY

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OBJECTIVES: To present the critical points concerning organizational and economic issues of the introduction of boceprevir in the treatment of patients with genotype 1 chronic hepatitis C in Italy. **METHODS:** A budget impact analysis was conducted adapting the NICE (UK) scheme for this drug, using the Italian epidemiological context and the perspective of the National Health Service. The cost-utility analysis (CUA) was carried out using a Markov model comparing the triple therapy (TT) with peginterferon alfa, ribavirin and boceprevir to the double therapy (DT) with peginterferon alfa and ribavirin. Available Italian published scientific literature provided data source. The main outcome of the CUA was the incremental cost-effectiveness ratio (ICER). The organizational aspects